10/17/00 11/17/00

Please type a plus sign (+) inside this box → ⊞

PTO/SB/16 (2-98)
Approved for use through 01/31/2001. OMB 0651-0037
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
DONALD J	HACKMAN	COLUMBUS OHIO
ROBERT A	DIXON	POWELL OHIO

☐ *Additional inventors are being named on the ___ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

METHOD AND APPARATUS UTILIZING TAPERED SCREW SHANKS FOR NONMETALLIC SPINAL STABILIZATION

CORRESPONDENCE ADDRESS

Direct all correspondence to:

☐ Customer Number ____ → *Place Customer Number Bar Code Label here*

OR *Type Customer Number here*

☒ Firm or Individual Name	DONALD J HACKMAN				
Address	3499 KIRKHAM RD				
Address					
City	COLUMBUS	State	OHIO	ZIP	43221
Country	USA	Telephone	614-451-7251	Fax	

ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 9 ☒ Small Entity Statement

☒ Drawing(s) *Number of Sheets* 3 ☐ Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☒ A check or money order is enclosed to cover the filing fees — FILING FEE AMOUNT ($): 75

☐ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: ____

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☐ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: ____

Respectfully submitted,

SIGNATURE Donald J Hackman Date 10/14/2000

TYPED or PRINTED NAME DONALD J HACKMAN REGISTRATION NO. *(if appropriate)*

TELEPHONE 614-451-7251 Docket Number:

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C., 20231.

Exhibit A

PTO/SB/17 (12/99)
Approved for use through 09/30/2000. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2000

Patent fees are subject to annual revision.
Small Entity payments must be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12.
See 37 C.F.R. §§ 1.27 and 1.28.

TOTAL AMOUNT OF PAYMENT ($)

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	ROBERT A. DIXON, D.O.
Examiner Name	
Group / Art Unit	
Attorney Docket No.	

METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number: _____

Deposit Account Name: _____

☐ Charge Any Additional Fee Required Under 37 CFR §§ 1.16 and 1.17

2. ☐ **Payment Enclosed:**
☒ Check ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	690	201	345	Utility filing fee	
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	690	208	345	Reissue filing fee	
114	150	214	(75)	Provisional filing fee	75

SUBTOTAL (1) ($) 75

2. EXTRA CLAIM FEES

	Extra Claims		Fee from below	Fee Paid
Total Claims	____ -20** =	____	X ____	= ____
Independent Claims	____ - 3** =	____	X ____	= ____
Multiple Dependent			____	= ____

**or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	78	202	39	Independent claims in excess of 3
104	260	204	130	Multiple dependent claim, if not paid
109	78	209	39	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	380	216	190	Extension for reply within second month	
117	870	217	435	Extension for reply within third month	
118	1,360	218	680	Extension for reply within fourth month	
128	1,850	228	925	Extension for reply within fifth month	
119	300	219	150	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,210	241	605	Petition to revive - unintentional	
142	1,210	242	605	Utility issue fee (or reissue)	
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	690	246	345	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	690	249	345	For each additional invention to be examined (37 CFR § 1.129(b))	

Other fee (specify) _____

Other fee (specify) _____

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	DONALD J HACKMAN	Registration No. (Attorney/Agent)	NONE	Telephone	614 451 7251
Signature	Donald J Hackman			Date	OCT 14 2000

WARNING:

Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/09 (12-97)
Approved for use through 9/30/00. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b)) - INDEPENDENT INVENTOR	Docket Number (Optional)

Applicant, Patentee, or Identifier: DONALD J HACKMAN

Application or Patent No.: _____

Filed or Issued: _____

Title: METHOD AND APPARATUS UTILIZING TAPERED SCREW SHANKS FOR NONMETALLIC SPINAL STABILIZATION

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- [X] the specification filed herewith with title as listed above.
- [ ] the application identified above.
- [ ] the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below

- [X] No such person, concern, or organization exists.
- [ ] Each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

ROBERT DIXON, DO	DONALD J HACKMAN	
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Signature of inventor	Signature of inventor	Signature of inventor
10-16-00	10-14-00	
Date	Date	Date

Cervical plastic provisional patent

Method and apparatus utilizing tapered screw shanks for nonmetallic spinal stabilization

Inventors: Robert A. Dixon

Donald J Hackman

U.S. Cl 606/61

ABSTRACT

A device and a method for stabilizing cervical vertebrae in a human spine for the purpose of fixing one vertebra with respect to other vertebrae and with respect to other parts of the spinal column. This device comprises a plate and bone screws fabricated from non metals. The bone screws maintain the plate in contact with the vertebrae. A tapered screw head is pulled into a machined tapered hole, locking the screw to the plate. The taper is configured to be self-locking preventing the screw from backing out.

FIELD OF THE INVENTION

The invention relates generally to implantable medical devices and their methods of use for stabilizing skeletal bone, and relates more particularly to implantable medical devices fabricated of nonmetals and their use for stabilizing the cervical vertebrae of a human spine.

BACKGROUND OF THE INVENTION

With normal anatomy, the vertebrae of the cervical column are held together and to the skeleton by a complex arrangement of ligaments, tendons and muscles. Degenerative diseases, deformities, or trauma may cause abnormal conditions. These problems generally cause or allow displacement or rotation of a vertebra relative to the adjacent vertebra. When spinal discs rupture or bulge the intervertebral space between two adjacent vertebras **31** and **32** can decrease and cause discomfort to the patient. Frequently the bulging does no harm, but if it compresses against the spinal cord or a nerve it may cause pain with loss of sensation, or weakness. When surgery is needed, the discs are replaced with implants that will heal or "fuse" together. This implant, with its associated stabilization, maintains the vertebral position while healing takes place. This is

referred to as "spinal fusion". The objective of spinal implants is to facilitate realignment and/or fixation of spinal elements. Clinical studies have demonstrated that surgeries using spinal implants are more effective at maintaining alignment and providing rigidity to the spine than surgeries in which implants are not used. Since the introduction of stabilizers as crude plates, rods, and wires, these devices have been developed into sophisticated appliances, which can be assembled and configured to rigidize spines of any size or condition. These stabilizers provide mechanical fixation for restraint of an implanted graft material. With this fixation, displacement during healing is significantly reduced thereby reducing the failure rate.

The majority of existing cervical stabilizers use plates that are bent in both the axial plain to conform to the vertebrae, and along the spinal axes to maintain lordosis.
Bicortical screw purchase has been favored because of the increased strength of the construct and increased screw thread area within the bone. These screws are more technically challenging to place and add increased risk of morbidity from neural canal penetration and screw backout. The reduced strength and decreased thread area of a unicortical screw purchase increases the probability of screw back out or loosening resulting in esophageal injury. Screw back out and loosening have led to the development of mechanisms for locking the screw head to the plate in unicortical screw plate designs. Such locking mechanisms not only prevent screw back out they also reduce the tendency of the screw head to pivot within the plate. These devices contain many intricate components that increase the cost and reduce reliability. The unicortical devices presently available are relatively rigid devices.

Nonmetals are preferred because of the minimal interference with X-rays and magnetic resonant imaging (MRI) techniques used for postoperative evaluation. Bendability or precurvature of the plate is also desired to accommodate or restore the natural lordosis of the cervical spine. These, and other desirable features and advantages, are provided by the present invention, particular embodiments of which are described below.
The plate is not needed once complete fusion has taken place. Indeed it is undesirable

because it may interfere with esophageal action or may later fracture resulting in esophageal injury. A fractured bone that has been has been fixed with a metallic stabilizer is much more likely to refracture if the stabilizer is removed. Refracture may occur because the stress sharing or stress shielding that the metal stabilizer provided during healing has not allowed the bone to carry sufficient load to return to full strength. The compression forces should be gradually transferred from the stabilizer to the healing bone. Bioabsorbable and biodegradable materials offer the potential of reabsorption into the bone or a gradual reduction of the plate and screw material after fusion and thus eliminate internal injury, a second operation, refracture, magnetic and radiographic artifact, and allows temporal load share promoting bony maturation and strengthening.

SUMMARY OF THE INVENTION

A device and a method for stabilizing cervical vertebrae in a human spine for the purpose of temporarily fixing the vertebra with respect to other vertebrae and with respect to other parts of the spinal column. This device comprises a curved nonmetallic plate and bone screws fabricated from non-metals. The plate has a plurality of tapered holes with the smaller diameter end adjacent to the vertebra and the larger diameter near the esophagus. The bone screw has a threaded portion that engages a predrilled and threaded hole in the vertebra or the graft. The bone screw also has tapered portion with a major diameter greater than the large diameter of the tapered hole. The bone screw maintains the plate in contact with the vertebra. The screw tapered portion is pulled into a matching tapered plate hole locking the screw to the plate. The taper is configured to be self-locking preventing the screw from backing out.

OBJECTS OF THE PRESENT INVENTION

An object of the present invention is to provide a method and device for a fusion, fixation and/or for spinal stabilization.

Another object of the present invention is to provide a stabilizer device which will degrade and disappear once the bones have healed.

Another object of the present invention is to provide a spinal fusion and a spinal stabilization using harvested bone, absorbable implants and nonmetallic stabilization plates and plate attachment devices.

Another object of the present invention is to provide devices and methods for cervical, thoracic, and lumbar spinal fusions anterioraly, posteriorly, and/or laterally.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood better from the following detailed description of the preferred embodiment. In the accompanying drawings the reference numbers refer to the individual parts described in the text.

FIG. 1 is a side section view at, 1-1, of the nonmetallic spinal stabilization system shown implanted on the cervical portion of a human spinal column.

FIG. 2 is a front (proximal) of view of the plate

FIG.3 is an end section view at, 3-3, of the nonmetallic spinal stabilization system shown with the vertebrae removed.

FIG. 4a is an end section view, at 4-4, of the plate with a "V" shaped posterior side.

FIG. 4b is an end section view, at 4-4, of the plate with a curved posterior side.

FIG. 5a is an enlarged partial section view of the bone screw with wrench socket and a shearable head.

FIG. 5b is an enlarged section view of the bone screw wrench socket in the tapered portion.

FIG. 5c is an enlarged section of the bone screw with a buttress thread.

FIG 5d is a top view of the bone screw showing a socket head wrench fitting.

FIG. 6 is an enlarged view of a bone screw with two tapered sections.

FIG. 7 is a front (proximal) of view of a two level plate.

FIG. 8 is a side section view of a two level plate with a matching lordordotic curvature.

DETAILED DESCRIPTION OF THE INVENTION

For simplification the stabilizer system is described as a cervical stabilizer in one of many conceivable embodiments. That is not to imply that this is the only embodiment within which the stabilizing system can be configured. For consistency in this patent the word stabilizer refers to the plate screw assembly, whereas the word graft refers to the material replacing the removed disc or vertebrae. This device comprises a plate and bone screws fabricated from polymeric, plastic, biodegradable, bioabsorble, human tissue, allograft, autograft or composite material.

The device

Referring to FIGS. 1, 2, and 3 in the preferred embodiment, the system is attached to the anterior surface of the spine **29**. The system **10** may be modified for use on the lateral aspects of the spine. The system comprises plate **12** and bone screws **20**. The system **10** and its components are described in detail in the following paragraphs. The bone stabilizing method of implanting is described in a subsequent section of this document.

Referring to FIGS. 1, 2, and 3, in particular the anterior cervical plate system **10** is shown in combination with bone screws **20**. Each of the plate **12** tapered holes **13** receives a bone screw. Bone screws **20** each include a head **23** and a threaded portion of the shank **21** and a tapered shank portion **22** between the head **23.** The tapered section **22** head **23** has a minor diameter that exceeds the major diameter of the threads of shank **21.** These diameters allow the bone screws **20** to be inserted, shank first, into any of screw holes **13** from the anterior side **11** of plate **12**, with the threaded shank **21** passing through the hole **13** of the posterior surface. The thread engages a predrilled and prethreaded hole **33** in the vertebra or the graft **30**. The bone screw maintains the plate **12** in contact with the vertebra **31** and **32**. The screw tapered portion **22** is pulled into the matching tapered plate hole **13** locking the screw **20** to the plate **12**. The taper is configured to be self-locking preventing the screw from backing out.

The plate

The plate **12** is the framework upon which the bone screws **20** are attached. The plate **12** has two holes **13** per vertebra, parallel to the patient's spinal axis to receive and contain the bone screws **20**. In the preferred embodiment the plate **12** is fabricated from a single piece of material. In prior art these plates were metal and contained threads for locking the screw or small locking devices such as cams were used to prevent the screws from backing out under sustained movement of the patient. Some nonmetallic materials do not have the yield, tensile, compressive, endurance, or shear strengths required to maintain the clamping force of the small area of screw threads, and are easily stripped during installation of the screw lock. To eliminate the use of plate threads on these materials the screw **20** is held in place with a locking taper **22** on the shank of the screw allowing the use of the full thickness of the plate for holding area. A locking cap can be used. On the materials that have sufficient strength for threads,

The plate may be curved **19** or shaped to allow for stabilizing the spine or positioning individual vertebra as required. Plate **12** is curved **19** and **20** such that posterior surface of the plate is generally concave and anterior surface **11** is generally convex. The radius of curvature in the longitudinal plane **18** is selected to match the desired lordosis of the section of the cervical vertebral column to which plate **12** is affixed. The radius of curvature in the transverse plane **19** is selected to conform to the transverse curvature of the anterior surfaces of the cervical vertebrae. The transverse curvature may be in the form of a v-shaped bend, as illustrated in FIG. **4a** or a curved surface **19** as illustrated in FIG. **4b**. The plate can also be fabricated in a two level plate **47** as shown in FIG 7 and FIG. 8 or more levels.

The bone screw

In the preferred embodiment the bone screw, may use cylindrical or tapered bone screw threads **21,** at the bone end **31**. and a tapered section **22** at the unthreaded portion of the shank, with a head which will accept a driving tool **25**. The head is attached to the tapered section with a small stem **27** which will shear off when the screw torque has reached the amount required to properly seat the taper within the plate hole **13.** The head

breaks off to assure that the bone threads are not tightened excessively, the wrench socket is not within the tapered section reducing its strength, and the head does not protrude into the esophagus.

A bone screw **20** is threaded into a drilled and tapped hole in a selected vertebra **31** to fix it into the position where it is threaded into a vertebra **31** and **32.**

The material

In light of the inherent disadvantages of a metal stabilizer described in the background section of this patent, plastic biodegradable or bioabsorbable materials may alleviate many or all of these problems. This device comprises a plate and screws which may be fabricated from polymeric, plastic, biodegradable, bioabsorble, human tissue or composite material.

A biodegradable, bioabsorbable, material which provides mechanical strength to bones while also providing a guide for growth of bone tissue. Preferably, the plate is formed of biodegradable materials. Poly(L-lactic acid), poly (lactic-co-glycolic acid), and poly (glycolic acid) are approved for human use by the Food and Drug Administration. These biodegradable products either enter metabolic pathways and are thereby eliminated from the body (bioabsorbed) or are eliminated from the body by other natural processes (e.g. in the urine).

Polyanhydrides maintain their mechanical strength for a longer time than the above polymers, by protecting the inner molecules from degradation with less porosity and greater component thickness. These materials degrade from the surface giving a reduced rate of degradation.

A polymeric matrix formed of a high molecular weight poly(L-lactic-acid) dispersed with a pore-creating substance formed of a low molecular weight poly(lactic acid) can be mixed to control the rate of digredation. Poly(glycolic acid) may have mechanical strength suitable for replacement of load-bearing bone for implantation, and it has a biodegradation rate about four times greater than the biodegradation rate of the

polymeric matrix.

LactoSorb® copolymer is an absorbable co-polymer synthesized from all-natural ingredients: 82% L-Lactic acid and 18% glycolic acid. Unlike the homopolymers in common use such as 100% poly-L-lactic acid (PLLA) or 100% poly-glycolic acid (PGA), LactoSorb® copolymer is amorphous (without crystallinity), which gives it a uniform degradation rate. Crystalline release associated with degrading homopolymers have been implicated in inflammatory reactions.

LactoSorb® co-polymer ratios permit the polymer to retain most of its strength for six to eight weeks, which is appropriate for healing, but not so long as to raise concerns about long-term stress bone shielding. Mass loss, which always follows strength loss for absorbable polymers, occurs in approximately twelve months for LactoSorb® copolymer. LactoSorb® is registered trade marked material of Arthrotek® a Biomet Company.

The graft

After removing the disc and the cartilage, a graft **30**, preferably a non-degrading bone growth-compatible material is positioned between the two vertebra **31** and **32** in the intervertebral space. Such grafts are structurally load-bearing devices, capable of withstanding the compressive forces supported by the adjacent superior vertebra **31**, however they will not provide the tensile force experienced at the vertebral to graft interface. The stabilizer **10** and the surrounding ligaments, tendons, and muscles must be preloaded to maintain compression between the graft and the adjacent vertebra during any upper body motion which tends to put the spinal cord in tension. The graft **30** must be in compressive contact with the vertebral end plates **31** and **32**. The graft **30** also may be metal, nonmetal, polymeric, allograft or autograft materials.

The Method

After the disc is removed the graft **30** is forced onto position at the center of the vertebral end plates **31** and **32.** Replacing damaged discs with rigid grafts is well known to those

practiced in the art. The method of stabilizing the graft and maintaining the relationship between the two vertebras is still a changing technology. The plate is selected and placed on the patient's vertebra **31** and **32**. Bushings **41**are inserted into the tapered holes **13** to align the drill and thread tap and to protect the tapered hole. The posterior side of the plate may be placed temporarily on the vertebra near the area where it will be attached and repositioned to determine the best location for the screws. The plate **12** with a guide bushing **41** is used as a template to guide the drill and tap at the position and angle of the matching screw holes. Once the holes are threaded, the screws **20** are threaded into the remaining holes. On frequently used plate sizes a metal template may be used to align the drill and tap.

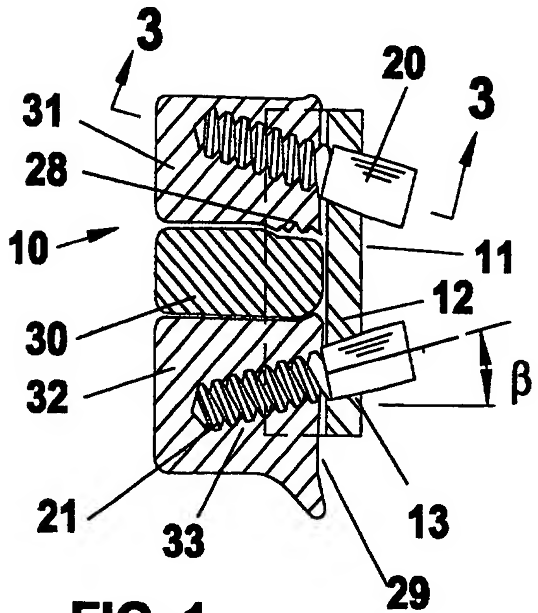

FIG. 1

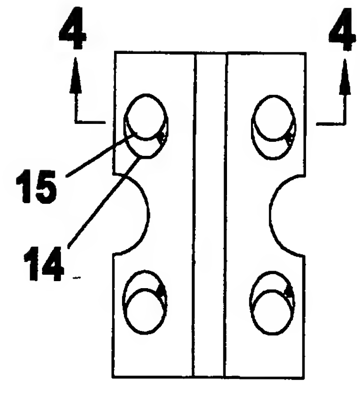

FIG. 2

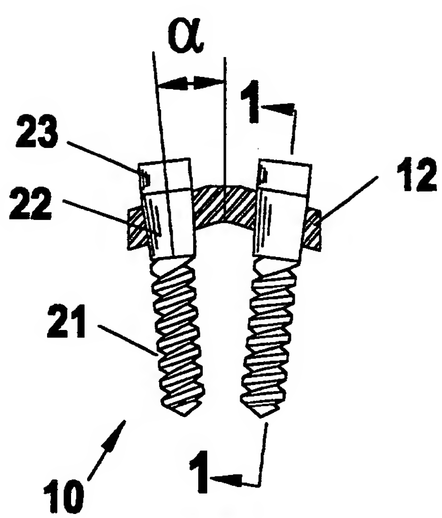

FIG. 3

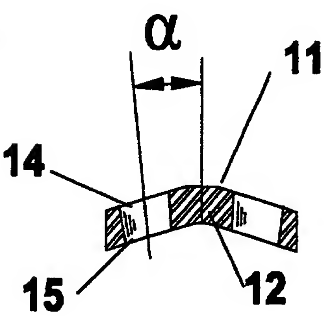

FIG. 4a

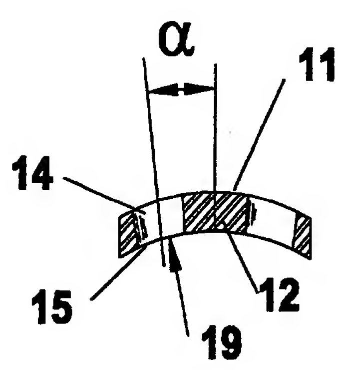

FIG. 4b

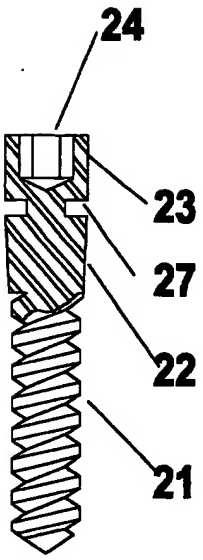

FIG. 5a

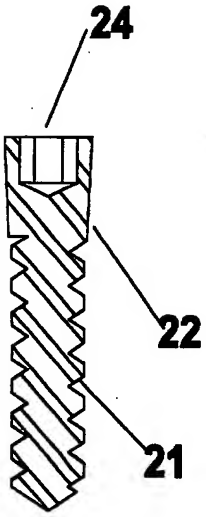

FIG. 5b

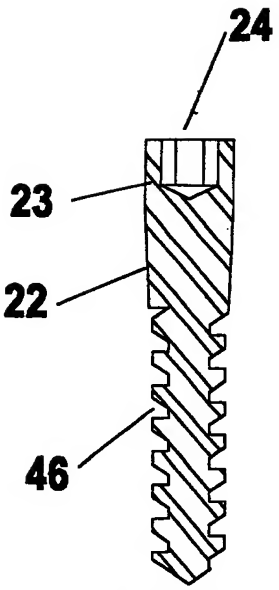

FIG. 5c

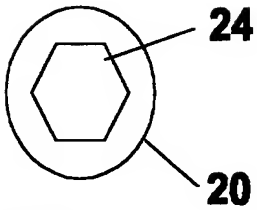

FIG. 5d

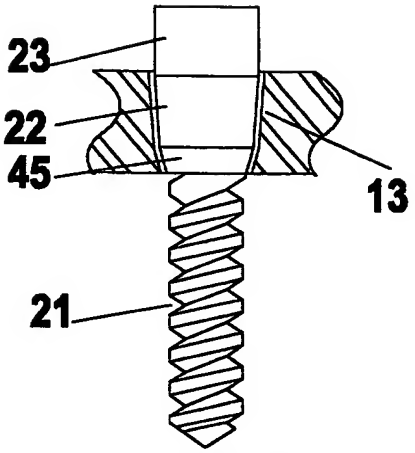

FIG. 6

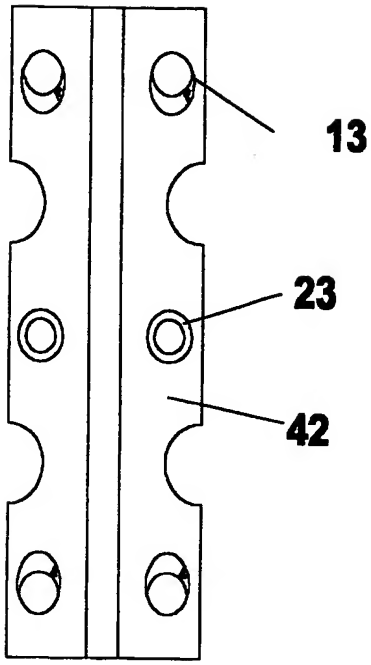

FIG. 7

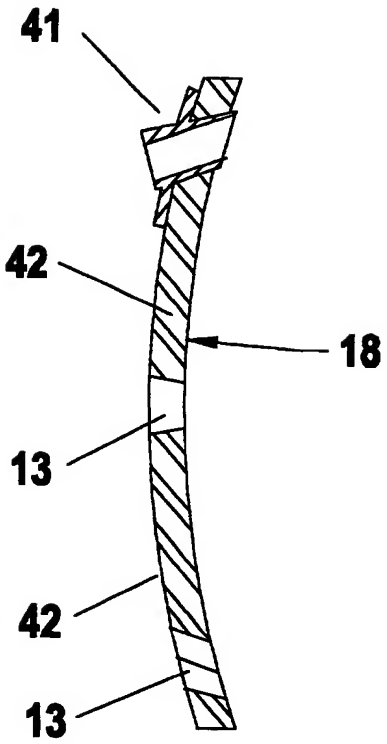

FIG. 8